UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

Office of pesticide Programs
Registration Division (7505P)

MEMORANDUM **DATA EVALUATION RECORD FOR #64864-AT**

July 26, 2012

Subject:	Name of the Product	eFOG-80 FDL
	EPA File Symbol:	64864-AT
	DP Barcode:	396221
	Decision No.	456487
	Action Code:	R320
	PC Codes:	071503

From: Masih Hashim, Team Leader-Toxicology MH
Technical Review Branch
Registration Division (7505P)
Byron T. Brown July-26-2012

To: Erin Malone, RM team 20
Herbicide Branch
Registration Division (7505P)

Applicant: Pace International, LLC
Seattle, Washington

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt
Fludioxonil	8.0
Other Ingredient(s)/impurities	92.0
Total:	100.0

Action Required: To evaluate the six acute toxicity studies for File Symbol ##64864-AT, eFog-80 FDL (with Fludioxonil for post harvest pome treatment by thermal fogging) as a proposed product by Pace International. The tox studies were conducted at Eurofins/PSL, Dayton, NJ. These studies were reviewed by an EPA contractor, Summitec Corporation, Knoxville, Tennessee. DERs were revised by TRB/RD.

The studies are in compliance with Sub-Division F guideline. The test material contained 7.9% active but we can accept 8% formulation.

Label

PRODUCT ID #: **064864-00067**

PRODUCT NAME: eFOG-80 FDL

PRECAUTIONARY STATEMENTS

SIGNAL WORD: **WARNING**

SPANISH SIGNAL WORD: AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Causes substantial but temporary eye injury. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear, specify appropriate protective eye wear*. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using toilet. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.
*(e.g., goggles, face shield, or safety glasses if appropriate).

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

DATA EVALUATION RECORD

FLUDIOXONIL
[EXC 6021]

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OCSPP 870.1100; OECD 425]
ACUTE DERMAL TOXICITY - RAT [OCSPP 870.1200; OECD 402]
ACUTE INHALATION TOXICITY - RAT [OCSPP 870.1300; OECD 403]
ACUTE EYE IRRITATION - RABBIT [OCSPP 870.2400; OECD 405]
ACUTE DERMAL IRRITATION - RABBIT [OCSPP 870.2500; OECD 404]
DERMAL SENSITIZATION - GUINEA PIG [OCSPP 870.2600; OECD 406]
MRID: 486306-03, 486306-04, 486306-05, 486306-06, 486306-07, and 486306-08

Prepared for
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Office of Pesticide Programs
U.S. Environmental Protection Agency
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Prepared by
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Task Order No. 3-B-83

Primary Reviewer:
Donna L. Fefee, D.V.M.

Signature: Donna L. Fefee, AE
Date: JUN 29 2012

Secondary Reviewers:
Robert H. Ross

Signature: Robert H. Ross
Date: JUN 29 2012

Robert H. Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: JUN 29 2012

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: JUN 29 2012

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

#64864-AT (P.C. Code 071503)

Reviewer: M. Hashim **Date: 7-25-12**

Risk Manager (EPA): 20

Acute Toxicity Data Evaluation Record (DER) for the six studies submitted for the proposed product

File Symbol #64864-AT.

1. DP BARCODE: 396221				
2. PC CODE: 071503				
3. CURRENT DATE: June 25, 2012				
4. TEST MATERIAL: EXC 6021; 7.9% Fludioxonil; "Formula: LBN 8093027-67"; EPSL Reference #110330-11H; light brown clear liquid; pH: 5.04 (1% w/w solution); specific gravity: 0.994 g/mL; expiration date: not provided; stored at room temperature and expected to remain stable for the duration of testing				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity / rat Eurofins PSL (Dayton, NJ) Study #32039 / July 13, 2011 OCSPP 870.1100; OECD 425	48630603	LD_{50} Females > 2000 mg/kg bw 5 females tested at 2000 mg/kg bw in accordance with AOT425 StatPgm limit test. No deaths, bw losses, or abnormal gross necropsy findings; abnormal clinical signs: reduced fecal volume in 1/5 animals on day 1, only.	III	A
Acute dermal toxicity / rat Eurofins PSL (Dayton, NJ) Study #32040 / July 13, 2011 OCSPP 870.1200; OECD 402	48630604	LD_{50} > 2000 mg/kg (both sexes) No deaths, bw losses, or abnormal gross findings; abnormal clinical signs: 1 female had red ocular discharge on days 9-10, and 1 female had erythema on the dose site on days 1-3 (with treatment on day 0).	III	A
Acute inhalation toxicity / rat Eurofins PSL (Dayton, NJ) Study #32041 / July 13, 2011 OCSPP 870.1300; OECD 403	48630605	LC_{50} (both sexes) > 2.04 mg/L Mean MMAD and GSD: 2.34 µm and 2.05; No deaths, abnormal clinical signs, or abnormal gross findings; BW: 1 male and 2 females lost or failed to gain wt during days 0-3 but did have net gain over days 0-14; a different male lost wt during days 7-14 and had net bw loss over days 0-14.	IV	A
Primary eye irritation / rabbit Eurofins PSL (Dayton, NJ) Study #32042 / July 13, 2011 OCSPP 870.2400; OECD 405	48630606	Severely irritating Classified based on corneal opacity on day 7 which cleared by day 10. "Positive" conjunctivitis was present in 3/3 eyes at 1-48 hrs and in 2/3 eyes at 72 hrs (redness=2, chemosis= 1-2, discharge=1-3); no positive conjunctivitis thereafter, and all eyes normal by 10 days post-instillation.	II	A
Primary dermal irritation / rabbit Eurofins PSL (Dayton, NJ) Study #32043 / July 13, 2011 OCSPP 870.2500; OECD 404	48630607	Classified based on absence of skin irritation at 72 hours. Slight irritant	IV	A
Dermal sensitization / guinea pig Eurofins PSL (Dayton, NJ) Study #32044 / July 13, 2011 OCSPP 870.2600; OECD 406	48630608	*Not* a sensitizer Tested using Buehler method 20 test animals/10 controls Induction and challenge used undiluted test material. Following challenge, no positive dermal reactions were seen on any treated or naïve control animals at either time point. Appropriate positive control study was provided.	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap